NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel*, Azam Rahimi and Radif Rashid, et al. Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA), INC., et al., Defendants.	:	Civil Action No. 15-6536-BRM-DEA **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before this Court is Defendant Zydus Pharmaceuticals (USA), Inc.'s ("Defendant" or "Zydus") Motion to Dismiss the First Amended Complaint of Plaintiffs/Relators Azam Rahimi ("Rahimi") and Radif Rashid ("Rashid") (together, "Relators"). (ECF No. 101.) Relators oppose the motion. (ECF No. 106.) Pursuant to Federal Rule of Civil Procedure 78(b), the Court did not hear oral argument. For the reasons set forth below, Defendant's motion is **GRANTED in part** and **DENIED in part**.

I. BACKGROUND

a. Procedural History

For the purposes of this Motion to Dismiss, the Court accepts the factual allegations in the Complaint as true and draws all inferences in the light most favorable to Plaintiff. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). On June 21, 2011, Rahimi filed in the United States District Court for the Eastern District of Texas an Original Complaint Pursuant to 31 U.S.C. §§ 3729-3732, Federal False Claims Act ("FCA") and Various State FCAs, and Pendant Claims

(the "Original Complaint"). (ECF No. 1.) The Original Complaint was filed on behalf of the United States of America, twenty-eight (28) states, the District of Columbia, and the City of Chicago. (*Id.*) On December 16, 2011, Rahimi filed a First Amended Complaint ("FAC") to, among other things, add Rashid as an additional relator. (ECF No. 9.) The FAC's factual allegations, however, are essentially unchanged from those in the Original Complaint. (*Compare id. with* ECF No. 1.)

On January 22, 2014, District Judge Richard A. Schell of the Eastern District of Texas lifted the seal on this action (ECF No. 12) after the Government filed a Notice of Election to Decline Intervention (ECF No. 10).[1]

While this action was pending in the Eastern District of Texas, on January 9, 2015, defendants moved to dismiss the FAC. (ECF No. 34.) By separate motion filed the same day, Zydus moved, in the alternative, to transfer venue to this Court. (ECF No. 41.) In response to the motion to dismiss, the Government filed a Statement of Interest. (ECF No. 48.) Relators opposed both the motion to dismiss and motion to transfer venue. (ECF Nos. 57, 58.) On August 6, 2015, Order granting defendants' motion to transfer venue was entered. (ECF No. 81.) Prior to ruling on the motion to dismiss, on August 28, 2015, District Judge Ron Clark of the Eastern District of Texas entered an Order overruling Relators' objections to the Order to Transfer Venue and transferring the case to this Court. (ECF No. 83.)[2]

[1] Subsequently, the case was transferred to the docket of District Judge Ron Clark of the Eastern District of Texas and referred to Magistrate Judge Caroline Craven for further proceedings. (ECF No. 51.)

[2] After the case was transferred to this Court, Relators reached an agreement to resolve their claims against defendants Mallinckrodt Pharmaceuticals, Tyco International, Ltd., Tyco Healthcare Group LP, and Covidien (collectively, the "Mallinckrodt Defendants"). (*See* ECF No. 117.) The Mallinckrodt Defendants were subsequently dismissed from the case (ECF No. 152), and Zydus is the only remaining defendant.

Zydus now moves to dismiss the FAC in its entirety pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(1) and 12(b)(6). (ECF No. 101.)[3]

b. Relators' Factual Allegations

Relators allege Zydus has been fraudulently inflating its prices for certain generic drugs[4] since 2005 by reporting inflated Average Wholesale Prices ("AWP") to various drug price publishers (the "Publishers") knowing Medicaid would rely on those prices to set reimbursement rates for Zydus's Generic Drugs. (ECF No. 9 at ¶¶ 2-3.) Relators allege Zydus sold the Generic Drugs to its retail customers at prices far lower than the prices it reported to the Publishers and the amounts that Medicaid ultimately reimbursed for the drugs. (*Id.* at ¶ 3.) Relators allege Zydus knowingly reported fraudulently inflated prices to ensure its retail pharmacy customers who dispense Zydus's Generic Drugs received inflated reimbursement and profits from Medicaid. (*Id.*) Relators further allege Zydus used the "spread" between its fraudulently inflated prices and the prices offered to retail customers as a means of inducing retail customers to purchase Zydus's Generic Drugs. (*Id.*)

The FAC alleges Zydus's nationwide fraudulent pricing scheme also inflated the reimbursement rates set by the federal government when establishing the Federal Upper Limit ("FUL") pricing ceilings for qualified generic drugs. (*Id.* at ¶ 4.) According to the FAC, the federal

[3] After Zydus's motion to dismiss was fully-briefed, Relators filed a Motion to Dismiss Count XXXIII, asserted on behalf of the City of Chicago. (ECF No. 116.) Because "the City ha[d] no objection to the dismissal, with prejudice, of Count XXXIII of Relators' First Amended Complaint, and to the dismissal, without prejudice, of the City as a party in the suit" (ECF No. 141), and no other opposition was filed, the Court granted Relators' motion on January 23, 2017. (ECF No. 152.)

[4] The generic drugs at issue include: Amiodarone Hydrochloride Tablets; Anastrozole Tablets; Carvedilol Tablets; Divalproex Sodium Capsules; Meloxicam Tablets; Paroxetine Tablets; Tamsulosin Hydrochloride Capsules; Topiramate Tablets; Venlafaxine Hydrochloride Tablets; and Warfarin Sodium Tablets (collectively, the "Generic Drugs"). (ECF No. 9 at ¶ 2.)

government uses the prices reported to the Publishers to establish the FUL reimbursement rates for generic drugs, and various state governments, in turn, rely on FUL when setting their Maximum Allowable Cost ("MAC") reimbursement rates for generic drugs. (*Id.*)[5]

In broad strokes, Relators allege Zydus's price inflation caused Medicaid programs to overpay, not only for the Generic Drugs at issue, but also for generic drugs in the same therapeutic class. (*Id.*)[6] As a result of Zydus's alleged price inflation, every state Medicaid program that factors in the FUL or AWP when determining reimbursement rates was caused to pay far more for the Generic Drugs than Zydus's retail customers. (*Id.* and at Ex. 13.)

Rahimi and Rashid have been pharmacists since 2007 and 2009, respectively. (ECF No. 9 at ¶¶ 6-7.) Rahimi opened his own pharmacy, Potomac Health Pharmacy, in Woodbridge, Virginia in November 2009. (*Id*. at ¶ 6.) "It was during the time [Rahimi] owned his own pharmacy that he discovered Defendant's alleged fraudulent pricing scheme." (*Id*.) Since receiving his pharmacy license, Rashid has worked as a pharmacist at his family's pharmacy, Fancy Pharmacy, in New York City. (*Id*. at ¶¶ 7-8.) As a pharmacist, "Rashid has worked with two wholesalers, Kinray, Inc. and AmerisourceBergen" and "receive[d] pharmaceutical pricing lists from these two wholesalers which include the list of available generic drugs, the drugs' manufacturer, and the related price." (*Id*. at ¶ 9.) When Rahimi "began processing the claims for the Zydus generic drugs[, he] discovered the Defendants' fraudulent pricing scheme." (*Id*.)

[5] Many states, such as New York, also use the reported AWP to establish their MAC. (ECF No. 9 at ¶ 4.)

[6] Attached as exhibits to the FAC are ten (10) invoices and claims submitted to New York Medicaid as representative examples purporting to show the inflated AWPs that Zydus reported to the publisher Blue Book. (ECF No. 9 at ¶¶ 57-66 and Exs. 3-12.) Relators allege that a comparison of the Medicaid claims and invoices to the prices paid by retail pharmacies shows spreads of up to 424%. (*Id.* at Exs. 1-2.)

Specifically, the FAC alleges "Rahimi began his initial investigation of the pricing disparity that appeared in several of the generic drug manufacturers' pricings offered to him at his former retail pharmacy . . . [which] led him to Zydus, a relatively new company to the generic manufacturers' marketplace." (*Id*. at ¶ 10.) "Rashid had also become aware of the pricing disparity and resulting higher reimbursement rates on Medicaid claims when he began processing claims at his pharmacy." (*Id*. at ¶ 11.) Relators "began discussing this issue of pricing disparity and higher reimbursement of the Medicaid claims for generic drugs" and "found that all of Rashid's claims had similar [sic] high reimbursement rates for Zydus's drugs." (*Id*. at ¶¶ 11-12.) Relators contend they "gained first-hand knowledge of Zydus' [sic] fraudulent pricing scheme through their investigation and have the claims documents that reflect that the Zydus drugs at issue are part of Zydus' [sic] alleged fraudulent pricing scheme." (*Id*. at ¶ 12.) This suit followed.

Zydus now moves to dismiss the FAC on the following grounds: (1) the Court lacks jurisdiction, pursuant to Federal Rule of Civil Procedure 12(b)(1), because Relators' claims are prohibited by the FCA's Public Disclosure Bar and Relators are not an original source; (2) the FAC does not satisfy the heightened pleading requirements for fraud claims of Federal Rule of Civil Procedure 9(b); and (3) Relators have failed to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). (ECF No. 101-1 at 7-29.) Zydus also moves to dismiss Relators' "parallel" state law claims on the same grounds. (*Id*. at 30-32.) Additionally, Zydus argues Relators are not authorized to bring many of the state law claims and many of those claims are time-barred. (*Id*. at 33-34.) Finally, Zydus argues the Court should decline to exercise supplemental jurisdiction over Relators' state law claims because their foundational federal claims lack merit and should be dismissed. (*Id*. at 34.)

II. LEGAL STANDARDS

a. Satisfaction of Rule 9(b)

For a fraud-based claim, a court may grant a motion to dismiss pursuant to Federal Rule of Civil Procedure 9(b) if the plaintiff fails to plead with the required particularity. *See Frederico v. Home Depot*, 507 F.3d 188, 200-02 (3d Cir. 2007). Based on the nature of their claims, Relators must satisfy the heightened pleading requirement of Rule 9(b), which requires that, "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). The heightened pleading standard gives defendants "notice of the claims against them, provides an increased measure of protection for their reputations, and reduces the number of frivolous suits brought solely to extract settlements." *In re Burlington Coat Factory Securities Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1996). Essentially, "[a] plaintiff must support allegations of fraud with all the essential factual background that would accompany the first paragraph of any newspaper story – that is, the who, what, where, and how of the events at issue." *Hemy v. Purdue Farms, Inc.*, Case No. 11-888, 2011 WL 6002463, at *13 (D.N.J. Nov. 30, 2011) (internal citations omitted).

b. Standard for Dismissal Pursuant to Rule 12

i. Federal Rule of Civil Procedure 12(b)(6)

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff]." *Phillips*, 515 F.3d at 228. "[A] complaint attacked by a . . . motion to dismiss does not need detailed factual allegations." *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007). However, the Plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a

formulaic recitation of the elements of a cause of action will not do." *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged." *Id.* This "plausibility standard" requires the complaint allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a 'probability requirement.'" *Id.* (citing *Twombly*, 550 U.S. at 556). "Detailed factual allegations" are not required, but "more than 'an unadorned, the defendant-harmed-me accusation" must be pled; it must include "factual enhancements" and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citing *Twombly*, 550 U.S. at 555, 557).

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

ii. Federal Rule of Civil Procedure 12(b)(1)

When considering a motion to dismiss for lack of jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1), "no presumpti[on of] truthfulness attaches to a plaintiff's allegations." *Martinez v. U.S. Post Office*, 875 F. Supp. 1067, 1070 (D.N.J. 1995) (citing *Mortensen v. First Fed. Sav. And Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977)). "Accordingly, unlike a Rule 12(b)(6) motion, consideration of a Rule 12(b)(1) motion need not be limited; conflicting written and oral evidence may be considered and a court may 'decide for itself the factual issues which determine jurisdiction.'" *Id.* (citing *Williamson v. Tucker*, 645 F. 2d 404, 413 (5th Cir.), *cert. denied*, 454 U.S. 897 (1981)). Nonetheless, "[w]here an attack on jurisdiction implicates the merits of plaintiff's federal cause of action, the district court's role in judging the facts may be more limited." *Martinez*, 875 F. Supp. at 1071 (citing *Williamson*, 645 F.2d at 413 n.6). Once a Rule 12(b)(1) challenge is raised, the burden shifts and the plaintiff must demonstrate the existence of subject matter jurisdiction. *PBGC v. White*, 998 F. 2d 1192, 1196 (3d Cir. 1993).

When a defendant moves to dismiss a claim for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1), the court must determine whether defendant is making a "facial or factual challenge to the court's subject matter jurisdiction." *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000); *Mortensen v. First Federal Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Under a facial attack, the movant challenges the legal sufficiency of the claim, and the court considers only "the allegations of the complaint and documents referenced therein and attached thereto in the light most favorable to the plaintiff." *Gould Elecs.*, 220 F.3d at 176; *Mortensen*, 549 F.2d at 891 ("The facial attack does offer similar safeguards to the plaintiff [as a 12(b)(6) motion]: the court must consider the allegations of the complaint as true.") The Court "may dismiss the complaint only if it appears to a certainty that the plaintiff will not be able to

assert a colorable claim of subject matter jurisdiction." *D.G. v. Somerset Hills Sch. Dist.*, 559 F. Supp. 2d 484, 491 (D.N.J. 2008) (citing *Cardio–Medical Assoc., Ltd. v. Crozer–Chester Med. Ctr.*, 721 F.2d 68, 75 (3d Cir.1983)).

Under a factual attack, however, the challenge is to the trial court's "very power to hear the case." *Mortensen*, 549 F.2d at 891. Thus:

> [T]here is substantial authority that the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case. In short, no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims.

Mortensen, 549 F.2d at 891. Moreover, in a factual attack, "the court may consider and weigh evidence outside the pleadings to determine if it has jurisdiction." *Gould Elecs.*, 220 F.3d at 178.

Regardless of the analysis, the plaintiff bears the burden of demonstrating the existence of subject matter jurisdiction. *See McCann v. Newman Irrevocable Trust*, 458 F.3d 281, 286 (3d Cir. 2006); *Lightfoot v. United States*, 564 F.3d 625, 627 (3d Cir. 2009) (citing *Carpet Grp. Int'l v. Oriental Rug Importers Ass'n*, 227 F.3d 62, 69 (3d Cir. 2000)).

Here, Defendants are asserting a facial 12(b)(1) challenge. They do not dispute the facts asserted by Plaintiff but rather argue that the claims asserted to not provide this Court with jurisdiction. This "facial" attack limits the Court's review to the pleadings and exhibits attached thereto, and the Court must consider the allegations in the light most favorable to Plaintiff. *Gould Elecs.*, 220 F.3d at 176; *Mortensen*, 549 F.2d at 891. Plaintiff bears the burden of proving subject matter jurisdiction, *McCann*, 458 F.3d at 286; *Lightfoot*, 564 F.3d at 627, and the Court must dismiss the complaint if it appears to a certainty Plaintiff cannot demonstrate a colorable claim of jurisdiction, *D.G.*, 559 F. Supp. 2d at 491.

III. DECISION

a. Relators' Claims Under the Federal FCA

"In broad strokes, the FCA imposes penalties on persons who knowingly submit fraudulent claims to the Government." *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 332 (3d Cir. 2005). "To encourage the ferreting out of fraud against the government, the FCA incentives private individuals aware of such fraud to bring [*qui tam*] civil actions as relators against those submitting such claims by allowing relators to collect a percentage of any recovery." *Id.* Here, Relators assert claims against Zydus under three provisions of the FCA and the "parallel" provisions of the various states' false claims statutes.

First, Relators allege Zydus violated 31 U.S.C. § 3729(a)(1)(A), which imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" (ECF No. 9 at ¶¶ 79-83, 115-18), by (1) causing pharmacies to present claims to the government "based on" AWPs "that were for substantially higher amounts of money than the retail pharmacies' actual acquisition costs" (*id*. at ¶ 79), and (2) creating a margin or "spread" between its AWPs and net prices for Generic Drugs as an "unlawful inducement" to have pharmacies purchase its prescription drugs in violation of the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(2)(B), amended by Pub L. 114-115, 129 Stat. 3131 (Dec. 28, 2015) (imposing liability on any person who "knowingly and willfully offers or pays any remuneration . . . to any person to induce such person . . . to purchase . . . any good . . . for which payment may be made in whole or part under a Federal health care program"). Second, Relators allege Zydus violated 31 U.S.C. § 3729(a)(1)(B), which imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" (ECF No. 9 at ¶¶ 84-110, 119-22), by (1) reporting false AWPs, which

were material to the claims pharmacies presented to the government (*id*. at ¶ 84), and (2) causing pharmacies to make false certifications of compliance with federal and state laws relating to Medicaid (*id*. at ¶¶ 84-5). Third, Relators allege Zydus violated 31 U.S.C. § 3729(a)(1)(C), which imposes liability on any person who "conspires to commit a violation" of the FCA (ECF No. 9 at ¶¶ 111-14, 123-24), by offering its pharmacy customers significant discounts off AWPs as an incentive to purchase its prescription drugs instead of its competitors' drugs.

Zydus raises several arguments in support of dismissal. First, Zydus argues FAC should be dismissed for lack of subject matter jurisdiction, pursuant to Federal Rule of Civil Procedure 12(b)(1), because Relators' allegations of AWP-fraud are based upon public disclosures in qualifying sources, and Relators are not an original source(s) of disclosures concerning AWP. (ECF No. 101-1 at 10-17.) Specifically, Zydus asserts numerous AWP-fraud lawsuits have been filed against drug manufacturers since 1995, including at least four (4) *qui tam* suits brought on behalf of the federal government, three (3) class actions by private insurers, a federal MDL in the District of Massachusetts[7], and twenty-seven (27) cases filed by state Attorneys General.[8] (ECF No. 101-1 at 10 and Appendix A.) Similarly, Zydus argues, since at least 1984, the federal government "has published dozens of public reports and statements characterizing AWP as a 'list price' or 'sticker price' and examining the relationship between AWPs and net drug prices" and, "since 1985, numerous Congressional committees have held hearings and issued reports examining AWP, its role in Medicare and Medicaid reimbursement, and its impact on federal healthcare program expenditures for prescription drugs." (*Id*. at 12 and Appendix B.) And, "[e]ven

[7] *See In re Pharmaceutical Industry Average Wholesale Price Litig*., MDL No. 1456 (D. Mass.)

[8] The following states on behalf of which Relators bring suit have filed AWP cases: California, Connecticut, Florida, Hawaii, Illinois, Iowa, Louisiana, Massachusetts, Minnesota, Montana, Nevada, New Jersey, New York, Oklahoma, Texas, and Wisconsin. (ECF No. 101-1 at 10 n.11.)

before the first AWP lawsuits, articles in numerous newspapers, magazines, and trade publications" allegedly reported on AWPs and their relationship to and impact on Medicare and Medicaid reimbursement. (*Id*. at 13-14.) Zydus argues Relators' allegations are based on these public disclosures and Relators lack any independent or direct knowledge concerning the alleged AWP fraud. (*Id*. at 14-20.)

Next, Zydus contends the Court should dismiss Relators' FCA claims for failing to state a claim, pursuant to Federal Rule of Civil Procedure 12(b)(6), because Relators' allegations do not meet the particularity requirement of Rule 9(b). (*Id*. at 20-29.) According to Zydus, Relators fail to allege: (1) Zydus made a statement or caused the presentation of a "false" claim; (2) any "false" claim was actually presented to the government; and/or (3) Zydus's AWPs were material to any false claims presented to the government. (*Id*. at 21-27.) Zydus also argues Relators' allegations do not evidence an intent to induce its pharmacy customers to purchase any particular drug or other details of the alleged kickback and, further, "relators do not explain how Zydus' [sic] payment of alleged 'kickbacks' would have caused pharmacies to violate state Medicaid programs' rules and thereby submit 'false' certifications." (*Id*. at 28.) Zydus also argues "Relators have failed to allege facts regarding any agreement or 'meeting of the minds' between Zydus and its pharmacy customers." (*Id*. at 30.)

Finally, Zydus argues the Court should dismiss Relators' state law claims for the same reasons as their federal FCA claims and, additionally, because Relators are not authorized to bring certain of these claims and some are time-barred. (*Id*. at 30-34.) Alternatively, if the Court dismisses Relators' federal claims, Zydus argues the Court should decline to exercise supplemental jurisdiction over their state law claims. (*Id*. at 34.)

Relators oppose the motion, arguing none of the allegedly public disclosures mentions Zydus or information sufficient to identify Zydus. (Relators' Mem. (ECF No. 106).) Relators contend Zydus is not a party to any of the prior AWP-fraud lawsuits, is not mentioned in any of the government reports or hearings, and had not even begun selling the drugs at issue when the vast majority of the lawsuits were filed and reports published. (*Id*. at 1, 6-14.) Relators also contend none of the allegedly public disclosures disclose the price at which Zydus sold the Generic Drugs at issue to retail pharmacies, which Relators assert "is a crucial component to the fraudulent scheme [they] exposed." (*Id*. at 1.) Regardless of whether there were public disclosures, however, Relators argue they are nonetheless "original sources" because they have direct and independent knowledge of this information. (*Id*. at 14-17.) Finally, Relators argue the FAC pleads actionable Federal and State FCA claims, and their factual allegations are pled with sufficient particularity to satisfy Rule 9(b).

i. The FCA's Public Disclosure Bar

"In 1986, Congress sought '[t]o revitalize the *qui tam* provisions,'" *U.S. ex rel. Mistick PBT v. Housing Authority of City of Pittsburgh*, 186 F.3d 376, 382 (3d Cir. 1999) (quoting *U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1154 (3d Cir. 1191)), in an effort "to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits," *United States ex rel. Zizic v. Q2 Administrators, LLC*, 728 F.3d 228, 235 (3d Cir. 2013). As a result, Congress enacted 31 U.S.C. § 3730(e)(4)(A), which provides:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (2006) (the "Public Disclosure Bar"). Congress amended the provisions of the Public Disclosure Bar in 2010. *See* 31 U.S.C. § 3730(e)(4) (2010). As the Defendant acknowledges, "[t]he difference between the two versions of the public disclosure bar is largely procedural."[9] (ECF No. 101-1 at 8.) "Substantively, the 2010 amendments left the test for application of the public disclosure bar largely unchanged." (*Id*. at 9.) Under either version, then, "[t]he Public Disclosure Bar applies where: (1) information was publicly disclosed via a source listed in § 3730(e)(4)(A); (2) the public disclosure included an 'allegation or transaction' within the meaning of the statute; and (3) the complaint is 'based upon' those disclosures." *United States ex rel. Morgan v. Express Scripts, Inc.*, No. 05-1714, 2013 WL 6447846, at *4 (D.N.J. Dec. 9, 2013) (citing *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 519 (3d Cir. 2007)).

"Starting out with the first and second elements, [the Court] analyze[s] whether 'information was [publicly] disclosed via one of the sources listed in § 3730(e)(4)(A)." *Zizic*, 728 F.3d at 235 (quoting *Atkinson*, 473 F.3d at 519). By its plain terms, the Public Disclosure Bar covers "allegations . . . from the news media," 31 U.S.C. § 3730(e)(4)(A), as well as allegations filed as part of civil complaints, *see, e.g.*, *Paranich*, 396 F.3d at 334 (holding that "a complaint in a civil action falls into the context of 'criminal, civil, or administrative hearings' and is sufficiently public within the meaning of the [Public Disclosure Bar] to constitute a public disclosure").

"Moving on to the third element, [the Court] consider[s] whether the information publicly disclosed in the [qualifying source] constituted allegations or transactions of fraud." *Zizic*, 728 F.3d at 235. "An allegation of fraud is an explicit accusation of wrongdoing." *Id*. (citing *U.S. ex*

[9] The date of the allegedly false claim determines which version of the statute applies. *See In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 12-2418, 2015 WL 4997077, at *5 (D.N.J. Aug. 20, 2015).

rel. Dunleavy v. Cnty. of Del., 123 F.3d 734, 741 (3d Cir. 1997)). As such, "to constitute 'allegations or transactions' within the meaning of the Public Disclosure Bar, the public disclosure must either allege the actual fraud, or must allege both the misrepresented state of facts and the true state of facts such that an inference of fraud may be drawn." *Express Scripts*, 2013 WL 6447846, at *5 (noting "public disclosure of the material elements of a fraud claim has been found to be enough to bar a qui tam action even if the disclosure itself does not allege any wrongdoing") (citations omitted).

Significantly, the "based upon" component of the Public Disclosure Bar does not require that the publicly disclosed information be the actual and only basis of the relator's complaint. Rather, the relator's allegations "need only be 'supported by' or 'substantially similar to' the disclosed allegations and transactions." *Atkinson*, 473 F.3d at 519 (quoting *U.S. ex rel. Mistick PBT v. Housing Auth.*, 186 F.3d 376, 385-99 (3d Cir. 1999)). As such, the Third Circuit has expressly held that the phrase "based upon" does not mean "actually derived from," because such an interpretation would render the original source exception superfluous. *Mistick*, 186 F.3d at 385-88.

The Third Circuit "adopted a formula to represent when information publicly disclosed in a specified source qualifies as an allegation or transaction of fraud":

> If X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.

Zizic, 728 F.3d at 236 (quoting *Dunleavy*, 123 F.3d at 741 (quoting *U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994))). "The essential elements of the allegation of fraud [Z] are 'a misrepresentation [X] and a true [Y] state of facts.'" *Id*. (quoting

Atkinson, 473 F.3d at 519). "Thus, the public disclosure bar applies 'if either Z (fraud) or both X (misrepresented facts) and Y (true facts) are [publicly] disclosed by way of a listed source." *Id.*

Zydus argues "it is abundantly clear that allegations of industry-wide AWP 'fraud' have been extensively disclosed in dozens of qualifying sources." (ECF No. 101-1 at 14.) As Relators argue in opposition, however, "none of the materials that Zydus submits even mentions Zydus, much less the allegation that it reported inflated AWPs for the drugs at issue to Publishers while charging retail pharmacies significantly less and using the spread to induce business." (ECF No. 106 at 8.) The Court is not persuaded by Zydus's argument that it was immediately identifiable from these disclosures because it is allegedly "one of the largest pharmaceutical companies in the United States." (ECF No. 101-1 at 16.) Indeed, as Relators cogently argue, Zydus is not readily identifiable from these public disclosures because (1) Zydus is not one of the largest pharmaceutical companies in the United States (or even among the top 50 in terms of sales); (2) dozens of companies manufacture the drugs at issue; and (3) the vast majority of these materials were filed or published before Zydus even received FDA approval to sell the drugs at issue. (ECF No. 106 at 8-9.) At a minimum, these issues of fact cannot be resolved on the current record.

The Court also finds, contrary to Zydus's assertions, the public disclosures of industry-wide AWP-fraud do not provide the "essential elements" of Relators' claims – namely, Zydus's identity as an industry participant and the Generic Drugs and specific transactions at issue – sufficient to trigger the public disclosure bar. *See U.S. ex rel. Baltazar v. Warden*, 635 F.3d 866, 868 (7th Cir. 2011) ("As far as we can tell, no court of appeals supports the view that a report documenting widespread false claims, but not attributing them to anyone in particular, block *qui tam* litigation against every member of the entire industry."); *U.S. ex rel. Ven-A-Care v. Actavis Mid Atl., LLC*, 659 F. Supp. 2d 262, 267-78 (D. Mass 2009) (explaining courts have required more

targeted disclosure than allegations of industry-wide fraud to trigger the public disclosure bar); *U.S ex rel. Cooper v. Blue Cross & Blue Shield of Fla., Inc*., 19 F.3d 562, 565 (11th Cir. 1994) (holding that a general accounting office report discussing widespread Medicare fraud was not sufficient to trigger the public disclosure bar); *U.S. ex rel. Stinson, Lyson, Gerlin & Bustamante, P.A. v. Provident Life & Accident Ins. Co.*, 721 F. Supp. 1247, 1258 (S.D. Fla. 1989) (holding *qui tam* suit not barred where government reports did not disclose the defendant's name or its alleged fraudulent conduct).

The cases Zydus relies upon are distinguishable. In *Zizic*, for example, the Third Circuit held that "even if [defendants] were not actually identified in the [public disclosure], they were directly identifiable from" it because the industry at issue was "an industry of one" and the defendants were the only industry participants "during their respective contractual terms." *Zizic*, 728 F.3d at 238. Similarly, in *Express Scripts*, the district court found that defendants, pharmaceutical publishers, while not expressly named in prior disclosures, were identifiable from previous complaints because there were "only three pharmaceutical publishers" who published AWP prices. *Express Scripts*, 2013 WL 6447846, at *4; *see also Paranich*, 396 F.3d at 335 (finding the public disclosure bar applied where the prior disclosure "set out the same allegations against a common defendant); *U.S. ex rel. Feldstein v. Organon*, 364 F. App'x 738 (3d Cir. 2010) (applying the public disclosure bar because "the allegations in Feldstein's complaint are substantially similar to allegations that were publicly disclosed in earlier Raplon-related personal injury lawsuits against Organon"; *i.e*., the same product and party being sued in the *qui tam* action).

Compared to the "industry of one" in *Zizic*, or similarly small industry in *Express Scripts*, Relators allege the generic drug manufacturing industry is quite large. (*See* ECF No. 106 at 12 n.10 (noting "there were over 1,500 pharmaceutical and medicine manufacturing firms in the

United States").) Based on the size of the industry, among other things, the Court finds Zydus was not immediately identifiable from any of the prior disclosures in which Zydus was not specifically identified. *See Balthazar*, 635 F.3d at 867 (finding that a "statement such as 'half of all chiropractors' claims are bogus' does not reveal which half and therefore does not permit suit against any particular medical provider" because it "takes a provider-by-provider investigation to locate the wrongdoers"). More importantly, Zydus could not have been identified from these prior disclosures because Zydus had not yet begun to sell the Generic Drugs at issue when those disclosures were made. Accordingly, this Court finds there was no public disclosure of Relators' allegations.

ii. Original Source Exception to the Public Disclosure Bar

Irrespective of whether there was a public disclosure of Relators' allegations, the Court nonetheless finds the Public Disclosure Bar does not apply because Relators are an "original source" of the information alleged in the FAC. *See* 31 U.S.C. § 3730(e)(4)(A). An "original source" is defined as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B). The Third Circuit has "interpreted direct to mean 'marked by absence of an intervening agency, instrumentality, or influence: immediate.'" *Paranich*, 396 F.3d at 335 (quoting *Stinson*, 944 F.2d at 1160). To be "direct," the "knowledge must have arisen from [relator's] 'own efforts, . . . not by the labors of others, and . . . [must not be] derivative of the information of others.'" *Feldstein*, 364 F. App'x at 743 (finding relator was not an original source because he did not personally witness or participate in the alleged fraud, but acquired knowledge from emails and conversations with other employees).

To qualify as an original source, "the relator must possess substantive information about the particular fraud, rather than merely background information which enables a putative relator to understand the significance of a publicly disclosed transaction or allegation." *Stinson*, 944 F.2d at 1161 ("The paradigmatic 'original source' is a whistleblowing insider. This covers . . . individuals who are close observers or otherwise involved in the fraudulent activity.") (internal marks and citation omitted). The Third Circuit has cautioned "courts [to] be mindful of suits based only on secondhand information, speculation, background information or collateral research." *Atkinson*, 473 F.3d at 523 (internal marks and citation omitted). Accordingly, "[a] relator . . . cannot establish that he is an original source solely by relying on unsupported, conclusory allegations." *U.S. ex rel. Pritsker v. Sodexho, Inc.*, 2009 WL 579380, at *13 (E.D. Pa. Mar. 6, 2009), *aff'd*, 364 F. App'x 787 (3d. Cir. 2010).

Zydus argues Relators do not qualify as "original sources" because they did not voluntarily disclose any information to the government before filing this case and have not provided independent information that materially adds to the information already in the public domain. (ECF No. 101-1 at 17-20.) Additionally, "Zydus requests an opportunity to take discovery of Relators on their presumed contention that they are an original source of the information alleged in" the FAC. (*Id*. at 16-17 n.14.)

Initially, the FAC alleges Relators disclosed their allegations to various State governments prior to filing suit. (*See* ECF No. 9 at ¶¶ 140, 151, 162, 173, 184, 195, 206, 217, 228, 239, 250, 261, 272, 283, 294, 305, 316, 327, 338, 349, 361, 372, 383, 394, 405, 416, 428, 439.) Moreover, in response to Zydus's factual attack, Relators submit their pre-filing disclosure to the U.S. Department of Justice and U.S. Attorneys' Office, indicating they disclosed their allegations to the Federal government as well. (*See* Declaration of Joel M. Androphy (ECF No. 106-1).)

The FAC's factual allegations also show Relators have direct and independent knowledge of their allegations. Individuals can have direct knowledge by having "first-hand knowledge of the fraudulent misconduct," or by being "close observers." *Atkinson*, 473 F.3d at 520; *Stinson*, 944 F.2d at 1154. "Others may qualify if their information results from their own investigations." *Stinson*, 944 F.2d at 1161. Unlike the relator in *Express Scripts*, 2013 WL 6447846, at *12, who merely compared the publicly-available prices in one publication to the prices in another publication, Relators identified Zydus, the Generic Drugs at issue, the falsely-reported AWPs, the specific prices paid by Relators' pharmacies, the resultant spread, and specific claims submitted to Medicaid. This information was, for the most part, not publicly-available, nor can it be said Relators performed only an "eyeball" comparison of publicly-available price listings, as Zydus contends. To the contrary, Relators owned the pharmacies purchasing drugs from Zydus, personally placed orders for those drugs, personally filled prescriptions for Medicaid patients, personally observed Medicaid reimbursement for the drugs at issue, and were able to independently determine the resultant spread. *See Paranich*, 396 F.3d at 336-37 (finding relator had "direct knowledge of the billing scheme because he was involved in it").

In short, the information Relators provide in the FAC goes well beyond general discussions of pharmaceutical industry price inflation and materially adds to information within the public domain regarding Zydus's alleged AWP-fraud. As such, the Court finds the Public Disclosure Bar is not an impediment to Relators' FCA claims against Zydus.

iii. Sufficiency of Relators' Federal FCA Allegations

Having determined Relators' claims are not precluded by the Public Disclosure, the Court next turns to the sufficiency of Relators' allegations. Counts I-III of the FAC assert causes of action under 31 U.S.C. § 3729(a), alleging Zydus: (1) knowingly caused a false or fraudulent claim to be

presented to the government for payment or approval, in violation of 31 U.S.C. §§ 3729(a)(1) and (a)(1)(A); (2) knowingly made or used or caused false records or statements, and omitted material facts, to get such false or fraudulent claims paid by the government, or that were material to false or fraudulent claims presented to the government, in violation of 31 U.S.C. §§ 3729(a) and (a)(1)(B); and (3) conspired with its retail pharmacy customers by offering these customers significantly lower prices for the Generic Drugs as an inducement, while Zydus reported false and fraudulent prices to the Publishers knowing Medicaid relied on such prices to establish reimbursement rates, in violation of the AKS. By agreeing to the financial incentive of this price spread scheme, Relators allege Zydus and its retail pharmacy customers caused the submission of false or fraudulent claims to Medicaid, in violation of 31 U.S.C. §§ 3729(a)(3) and (a)(1)(C).

Zydus argues the Court should dismiss Relators' FCA claims because they fail to allege: (1) Zydus made a statement or caused the presentation of a claim that was "false"; (2) any "false" claim was actually presented to the government; and (3) the AWPs reported by Zydus were material to any false claims presented to the government. (ECF No. 101-1 at 20-27.) Additionally, Zydus argues Relators' AKS claims are not plead with particularity and their conspiracy claim fails to allege facts regarding any agreement or "meeting of the minds" between Zydus and its pharmacy customers. (*Id*. at 27-30.)

To state a claim under 31 U.S.C. § 3729(a)(1) of the FCA, a plaintiff must plead three elements: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment;[10] (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004).

[10] The FCA defines a claim, in pertinent part, as a "request or demand . . . for money or property that . . . is presented to an officer, employee, or agent of the United States . . ." 31 U.S.C. § 3729(c) (pre-Fraud Enforcement and Recovery Act, which expanded liability under the FCA).

"A § 3729(a)(3) claim requires specific intent; it does not require 'that the conspirators intended the false record or statement to be presented directly to the Government, but it must be established that they agreed that the false record or statement would have a material effect on the Government's decision to pay the false or fraudulent claim.'" *U.S. v. Albinson*, Civ. No. 09–1791, 2010 WL 3258266, at *10 (D.N.J. Aug. 16, 2010) (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008)).

FCA claims must be plead with particularity in accordance with Rule 9(b), *Schmidt*, 386 F.3d at 242 n.9, which requires "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). "To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007). Although Rule 9(b)'s requirements are stringent, "courts should be sensitive to situations in which sophisticated defrauders may successfully conceal the details of their fraud." *In re Rockefeller Ctr. Prop., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d. Cir. 2002) (internal marks omitted). Essentially, Rule 9(b) requires "plaintiffs [to] accompany their legal theory with factual allegations that make their theoretically viable claim plausible." *Id.* (citations omitted). Because the Court finds the FAC meets the Rule 9(b) standard, Relators' FCA claims will proceed.

Zydus first argues that, because "there is no statute, regulation, rule, or contract that defines AWP . . . Relators do not (and cannot allege that Zydus' [sic] AWPs were 'false' as a matter of law." (ECF No. 101-1 at 24.) But courts have consistently rejected the notion that AWPs can be defined as whatever price drug manufacturers chose to publish through pricing compendia. *See, e.g., Mass v. Mylan Labs.*, 608 F. Supp. 2d 127, 144 (D. Mass. 2008) (rejecting drug

manufacturers' proposed definition of wholesale acquisition costs as an undiscounted "list price" because it would give them "a virtual blank check" and finding "[t]he suggestion that the Commonwealth 'intended to give the pharmaceutical industry free reign over drug pricing' is absurd"); *In re Pham. Indus. Av. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 173 (D. Mass. 2007) (giving drug manufacturers "cart blanche to publish sky-high prices unmoored from the acquisition costs of providers leads to absurd results"); *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 163 (D. Mass. 2003) (commenting that the idea the government "would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and [others] is, to say the least, unusual").

Next, Zydus argues Relators have not alleged facts demonstrating that false claims were actually submitted to the government because "none of the claims attached to Relators' Amended Complaint includes or references an AWP." (ECF No. 101-1 at 25.) However, Exhibits 3 through 12 to the FAC, which are claims submitted by Rashid to New York Medicaid, all clearly show the reported AWP. (*See, e.g.*, ECF No. 9 at Ex. 3 (listing Blue Book's published AWP next to "BBAWP," or "Blue Book Average Wholesale Price".) Thus, the claims and invoices attached to the FAC provide a reliable indicia that false claims were presented to Medicaid.

Zydus also argues that, because none of the claims attached to the FAC were reimbursed based on AWP, Relators cannot show Zydus's reported AWP was material. This argument borders on the disingenuous, as Zydus itself concedes the federal government relies on AWP as a benchmark for reimbursement decisions. (ECF No. 101-1 at 22 (noting the government has "us[ed] or approv[ed] AWPs for decades as a benchmark for Medicare and Medicaid reimbursement"); *id.* at 3 n.2 (describing "AWP [as] the benchmark often used to set reimbursement for prescription drugs under [] Medicare").)

With respect to Relators' AKS claims, Zydus argues Relators "do not identify the pharmacies involved, the content of or date of any attempt to 'market the spread' or any 'unlawful inducement' to pharmacies, or the drugs at issue." (ECF No. 101-1 at 28.) But Rule 9(b) does not require such precision. Rather, "[w]here it can be shown that the requisite factual information is particularly within the defendant's knowledge or control, the rigid requirement of [Rule] 9(b) may be relaxed." *Albinson*, 2010 WL 3258266, at *14 (citing *Rockefeller*, 311 F.3d at 217). "[T]o meet the standards of Rule 9(b), . . . [Relators] must provide 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Fogila v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157-58 (3d Cir. 2014). The Court has already found that the claims and invoices attached to the FAC provide a reliable indicia that false claims were presented, and Relators provides more than sufficient details of the alleged scheme to put Zydus on notice of their claims.

Finally, with respect to Relators' conspiracy claim, "the allegations of the conspiracy need only satisfy the notice pleading standards of Rule 8." *U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, Civ. A. No. 94-7316, 2000 WL 1207162, at *10 (E.D. Pa. Aug. 24, 2000). The FAC easily provides such notice, by alleging the general composition of the conspiracy (ECF No. 9 at ¶ 123), its broad objectives (*id*. at ¶¶ 3, 53), and Zydus's general role in the conspiracy (*id*. at ¶ 53).

b. Relators' State Law Claims (Counts IV – XXXII)

In addition to their federal FCA claims, Relators also bring causes of action under the false claims acts of 28 states and the District of Columbia.[11] (ECF No. 9 at 47-126.) As Zydus concedes, there is "substantial similarity between the FCA and each of the state false claims statutes under which Relators bring suit." (ECF No. 101-1 at 30.) Thus, for the same reasons the Court declines

[11] Relators' claims on behalf of the City of Chicago were previously dismissed. *See* n.4.

to dismiss Relators' federal FCA claims, the Court likewise declines to dismiss Relators' "substantially similar" claims under the various states' *qui tam* statutes, because these statutes essentially mirror the federal FCA. Because the Court declines to dismiss Relators' federal claims, there is no basis for the Court to decline to exercise supplemental jurisdiction over Relators' "substantially similar" state-law clams. *See* 28 U.S.C. § 1367(a) (providing for "supplemental jurisdiction over all other claims that are so related to the claims in the [federal] action . . . that they form part of the same case or controversy"); 31 U.S.C. § 3732(b) ("The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730."). Where, as here, a complaint asserts both federal claims and state law claims, a district court has supplemental jurisdiction over all claims that "derive from a common nucleus of fact . . . such that [a plaintiff] would ordinarily be expected to try them all in one judicial proceeding." *Carnegie-Mellon Univ. v. Cohill*, 484 U.S. 343, 349 (1988) (quoting *United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 725 (1966)). It would be the height of inefficiency to force Relators to try their state law claims (which Zydus admits are "substantially similar" to the FCA claims) in a separate judicial proceeding.

The Court also finds Relators' state law claims satisfy the requirements of Rule 9(b), for the same reasons discussed above with respect to Relators' FCA claim. Additionally, the Court finds Relators have sufficiently alleged a nationwide scheme to defraud the government by alleging, among other things, information about drug pricing found in databases of wholesalers that provided services to pharmacies across the nation, as well as drug pricing in several states, including Virginia, New York, and Texas. Indeed, Zydus concedes Relators' claims under New York law allege "reliable indicia" that false claims were presented. (ECF No. 101-1 at 32.)

Nonetheless, Zydus argues Relators failed to allege "reliable indicia" that Zydus caused the presentation of false claims to any other state or municipality, and Relators must "allege some specificity with respect to each asserted state." (ECF No. 101 at 32 (quoting *U.S. ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 357 (D. Mass. 2011) (additional citations omitted).) The Court disagrees.

In *Nowak,* unlike here, the court found that, because the relator had not pled specific claims as to any state, it could not infer a nationwide scheme. *Nowak*, 806 F. Supp. 2d at 357 (noting "one judge in this District has found that specifically pled claims in one state are sufficient to support an inference of a nationwide scheme and the pleadings requirements for all state counts"). Similarly, in *U.S. ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472 (S.D. Tex. 2011), the court declined to dismiss certain federal claims or related state law claims predicated on the same theories because, although the relator's kickback allegations were all from Texas, the relator "alleged enough details of a geographically diverse kickback scheme to reliably indicate that there was a nationwide kickback scheme." *Id*. at 497, 519; *accord U.S. ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 906 F. Supp. 2d 1264, 1277 (N.D. Ga. 2012) (finding relator's complaint failed to allege a nationwide fraudulent billing scheme because relator had limited information regarding national billing policies and his firsthand knowledge was based only on his work with clinics in two states).

Unlike the complaints in *Nowak*, *King* and *Saldivar*, Relators' FAC includes several examples of pricing disparities between Medicaid reimbursement and wholesale pricing from wholesalers providing services to retail pharmacies across the nation, including Kinray and Amerisource Bergen. (ECF No. 9 at ¶¶ 10-11 and Exs. 3-12.) The Court finds these allegations are

sufficiently "reliable indicia" that false claims were presented to New York, as Zydus concedes, as part of a nationwide scheme to present actually false claims to the government.

Zydus next argues Relators' state law causes of action should be dismissed because "[e]ach state and municipal false claims statute under which Relators bring suit (save for the Louisiana statute) requires that the relevant state or municipality both decline to intervene and file a notice with the court . . . before a relator may proceed with a qui tam suit[,]" but those jurisdictions did not validly declined to intervene in this case. (ECF No. 101-1 at 33.) Zydus's argument has merit, but ultimately fails.

On January 23, 2012, the United States notified the Court of its decision not to intervene in this action. (ECF No. 10.) The United States' Notice of Election to Decline Intervention further states:

> [T]he undersigned government counsel has been advised by the following States that they also decline to intervene in this action: California, Connecticut, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, as well as the City of Chicago.

(*Id.*) Zydus argues the United States' filing did not validly decline intervention on behalf of the states, the District of Columbia, and City of Chicago because it fails to comply with the specific intervention procedures set forth in each jurisdiction's false claims act. In response, Relators simply refer the Court to the United States' filing, which Relators argue provided notice of the individual states' declination.

"When interpreting a statute, 'the literal meaning of the statute is the most important, and [courts] are always to read the statute in its ordinary and natural sense.'" *In re Harvard Indus., Inc.*, 568 F.3d 444, 451 (3d Cir. 2009) (quoting *Galloway v. United States*, 492 F.3d 219, 233 (3d

Cir. 2007)). Here, each jurisdiction's false claims act requires either the jurisdiction or an official thereof to notify the Court of that jurisdiction's decision to decline intervention.[12] Plainly, this

[12] Specifically, the California statute requires the state "Attorney General" to "notify the court that it declines to proceed with the action." Cal. Gov't Code § 12652(b)(3). The Colorado statute requires "the state" to "[n]otify the Court that it declines to take over the action, in which case the relator shall have the right to conduct the action." Colo. Rev. Stat. § 25.5-4-306(2)(d)(II). The Connecticut statute requires "the Attorney General" to "notify the court that the Attorney General declines to take over the action." Conn. Gen. Stat. § 17b-301d(a). The Delaware statute requires the state "Department of Justice" to "[n]otify the court that it declines to take over the action." 6 Del. Code § 1203(b)(4)(b). The District of Columbia statute requires the "Attorney General for the District of Columbia" to "[n]otify the court that he or she declines to take over the action." D.C. Code § 2-381.03(b)(4)B). The Florida statute requires the state "Department of Financial Services" to "[n]otify the court that it declines to take over the action." Fla. Stat. Ann. 68.083(6)(b). The Georgia statute requires the state "Attorney General" to "[n]otify the court that it declines to take over the civil action." Ga. Code Ann. §49-4-168.2(c)(4)(B). The Hawaii statute requires "the State" to "[n]otify the court that it declines to take over the action." Haw. Rev. Stat. § 661-25(d)(2). The Illinois statute requires "the State" to "notify the court that it declines to take over the action." 740 Ill. Comp. Stat. 175/4(b)(4)(B). The Indiana statute provides that, "[i]f the attorney general or the inspector general elects not to intervene in the action, the person who initially filed the complaint has the right to prosecute the action." Ind. Code §5-11-5.5-5(f). The Iowa statute requires "the state" to "[n]otify the court that the state declines to take over the action." Iowa Code Ann. § 685.3(2)(d)(2). The Maryland statute provides that, "[i]f the State does not elect to intervene and proceed with the action . . . before unsealing the complaint, the court shall dismiss the action." Md. Code Ann., Health-Gen § 2-604(7). The Massachusetts statute requires the state "attorney general" to "notify the court that he declines to take over the action." Mass. Gen. Laws Ann. Ch. 12 § 5C(4). The Michigan statute requires the state "attorney general" to "notify the court and the person initiating the action . . . [t]hat [he] declines to take over the action." Mich. Comp. Laws Ann. § 400.610a(3)(b). The Minnesota statute provides that "the prosecuting attorney shall intervene or decline intervention." Minn. Stat. §15C.06(a). The Nevada statute provides that the state "Attorney General or a designee of the Attorney General pursuant to NRS 357.070" must elect "whether to intervene." Nev. Rev. Stat. Ann. §357.080(4). The New Hampshire statute requires the "state" to "[n]otify the court that it declines to take over the action." N.H. Rev. Stat. Ann. § 167:61-c(II)(e)(2). The New Jersey statute provides that the state "Attorney General shall . . . file a pleading with the court that he declines to proceed with the action." N.J.S.A. 2A:32C-5(g)(2). The New Mexico statute provides the state "attorney general or political subdivision shall notify the court that the state . . . declines to take over the action." N.M.S.A. § 44-9-5(D)(2). The New York statute provides that, "[i]f the state declines to participate in the action or to authorize participation by a local government, the qui tam action may proceed." N.Y. Stat. Fin. Law § 190(2)(f). The North Carolina statute provides that, "[i]f the State elects not to proceed with the action, the qui tam plaintiff shall have the right to conduct the action." N.C. Gen. Stat. § 1-609(f). The Oklahoma statute requires the "state" to "notify the court that it declines to take over the action." Okla Stat. Ann. tit. 63 § 5053.2(B)(4)(b). The Rhode Island statute requires the "state" to "[n]otify the court that it declines to take over the action." R.I. Gen. Laws Ann. § 9-1.1-4(b)(4)(ii).

procedure was not complied with prior to filing suit, as only the United States notified the Court of its election to decline intervention. (ECF No. 10.) In a recent decision, District Judge Jose L. Linares of this Court found, under similar circumstances, that a "Joint Notice of Election to Decline Intervention" filed by the Acting Attorney General for the State of New Jersey purportedly on behalf of the District of Columbia and every state (except Texas) named in the action was insufficient to comply with the relevant state's false claims acts. *See U.S. ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2014 WL 1418293, at *11 (D.N.J. Apr. 11, 2014) (finding the requisite notice procedures in each state's false claims act was not complied with and dismissing without prejudice relator's claims under those statutes where only the Acting Attorney General of New Jersey purported to notify the court of those states' elections not to intervene). The same reasoning applies to this case, and the Court finds the United States' Notice of Election to Decline Intervention does not comply with the procedures set forth in each jurisdiction's false claims act.

After Zydus's motion was fully-briefed, however, the Court received formal notice from the following States advising they also decline to intervene in this action: California, Connecticut, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire,

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The Tennessee statute requires the "attorney general and reporter" to "[n]otify the court that it declines to proceed with the action." Tenn. Code Ann. §4-18-104(b)(3)(B). The Texas statute provides that "the state shall . . . notify the court that the state declines to take over the action." Tex. Hum. Res. Code § 36.104(a)(2). The Virginia statute requires the "commonwealth" to "notify the court that it declines to take over the action." Va. Code Ann. §8.01-216.5(D). The Wisconsin statute requires the "attorney general" to "[n]otify the court that he or she declines to proceed with the action." Wis. Stat. Ann. § 20.931(5)(d)(2). Lastly, the Chicago statute provides that "the city shall . . . notify the court that it declines to take over the action." Municipal Code of Chicago § 1-22-030(b)(4)(B). Additionally, although Zydus did not move to dismiss Relators' claims under Louisiana law (Count 15), the Court notes the Louisiana statute also provides that, "[i]f the secretary [of the Department of Health and Hospitals, or his authorized designee,] or the attorney general does not intervene, the qui tam plaintiff may proceed with the qui tam action," La. Rev. Stat. Ann. § 46:439.2(B)(4)(b).

New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin. (*See* ECF Nos. 120 to 140, 142 to 144, 146.)

Although the Court finds the United States' omnibus Notice of Election to Decline Intervention (ECF No. 10) does not strictly comply with the requirements of each jurisdiction's false claims act, in light of the States' subsequent notices, and in the interest of judicial economy, the Court will allow these claims to proceed.

Finally, Zydus argues the Court should dismiss all of Relators state-law claims which accrued before the effective date of the relevant state's *qui tam* statute. Zydus contends the *qui tam* statutes of Connecticut, Georgia, Indiana, Iowa, Minnesota, Montana, New Jersey, New Mexico, New York, Oklahoma, and Rhode Island all took effect in or after 2005. (ECF No. 101-1 at 34.) With the exception of the Montana statute,[13] however, Zydus has failed to show why these remedial statutes should not be retroactively applied. Indeed, contrary to Zydus's arguments, both the New York and New Mexico statutes are expressly retroactive. *See U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 540 (S.D.N.Y. 2014) (concluding "the New York FCA has retroactive application" because, among other reasons, "[i]n enacting the New York FCA, the New York legislature provided that 'section thirty-nine of this act [which amended the New York Finance Law to add the New York FCA] shall apply to claims filed or presented prior to, on or after April 1, 2007'"); N.M. Stat. Ann. § 44-9-12 (authorizing a civil action to be brought for conduct that occurred prior to the effective date of the Act, but not for conduct that occurred prior to July 1, 1987). The Court finds retroactive application of the states' *qui tam* statutes would not be contrary to the legislative intent nor result in manifest injustice. *See Bradley v. Sch. Bd. of City*

[13] "Relators concede that the Montana FCA is expressly not retroactive and applies only to claims accruing after October 1, 2005." (ECF No. 106 at 34.)

of Richmond, 416 U.S. 696, 711 (1974). However, the Court will dismiss with prejudice Relators' claims under the Montana FCA (Count 20) which accrued prior to October 1, 2005.

IV. CONCLUSION

For the reasons set forth above, Defendant's Motion to Dismiss is **GRANTED in part** and **DENIED in part**. Relators' claims under the Montana FCA (Count 20) which accrued prior to October 1, 2005 are **DISMISSED WITH PREJUDICE**. Zydus's motion is **DENIED** in all other respects. An appropriate order will follow.

Date: April 25, 2017

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE